

IN THE CLAIMS

Please amend the claims as follows.

1 Claims 1-4 (canceled).

1 5. (New) A method for forming a pathway from a sub-intimal space of a blood
2 vessel into a true lumen of the blood vessel, comprising:
3 positioning a catheter system within the sub-intimal space at a position proximate
4 to a target entry site into the vessel true lumen, the catheter system including at least one
5 lumen in communication with at least one port in a distal region of the catheter system,
6 the catheter system further including an internal incising element that is translatable
7 across a portion of the port;
8 determining a radial position of the true lumen with respect to the port at the
9 target entry site from a position in the sub-intimal plane using an imaging device of the
10 catheter system; and
11 forming an incision in tissue separating the sub-intimal space from the true lumen
12 using the incising element, the incision having separate and distinct end points and
13 forming a pathway between the sub-intimal space and the true lumen, wherein the tissue
14 remains external to the port subsequent to forming the incision.

1 6. (New) The method of claim 5, wherein the imaging device is a rotational imaging
2 device.

1 7. (New) The method of claim 5, wherein the imaging device is an ultrasonic
2 device.

1 8. (New) The method of claim 5, wherein the imaging device is an optical
2 coherence tomography (OCT) device.

- 1 9. (New) The method of claim 5, wherein the incising element is integral to the
2 imaging device.
- 1 10. (New) The method of claim 5, wherein the incising element is separate from and
2 arranged concentrically outside the imaging device.
- 1 11. (New) The method of claim 5, wherein determining the radial position includes
2 use of an imaging device that is a fixed integral part of a body of the catheter system.
- 1 12. (New) The method of claim 5, wherein determining the radial position includes
2 use of a fluoroscopic marker on the catheter system.
- 1 13. (New) The method of claim 12, wherein the fluoroscopic marker is located on a
2 body of the catheter system.
- 1 14. (New) The method of claim 12, wherein the fluoroscopic marker is located on
2 one or more working elements of the catheter system.
- 1 15. (New) The method of claim 5, further comprising evacuating fluid from the sub-
2 intimal space and securing the tissue separating the sub-intimal space from the true lumen
3 at the port by applying vacuum to the catheter lumen.
- 1 16. (New) The method of claim 15, further comprising invaginating the tissue
2 separating the sub-intimal space from the true lumen into the port and into a distal
3 interior region of the catheter system upon application of the vacuum.
- 1 17. (New) The method of claim 5, further comprising advancing a working element
2 into the true lumen through the incision.
- 1 18. (New) The method of claim 17, wherein the working element includes at least
2 one of a guide wire and a cannula.

1 19. (New) A method for forming a pathway from a sub-intimal space of a blood
2 vessel into a true lumen of the blood vessel, comprising:
3 positioning a catheter system within the sub-intimal space at a position proximate
4 to a target entry site into the vessel true lumen, the catheter system including at least one
5 lumen in communication with at least one port in a distal region of the catheter system,
6 the catheter system further including an internal incising element that is translatable
7 across a portion of the port; and
8 forming an incision in tissue separating the sub-intimal space from the true lumen
9 using the incising element, the incision having separate and distinct end points and
10 forming a pathway between the sub-intimal space and the true lumen, wherein the tissue
11 remains external to the port subsequent to forming the incision.

1 20. (New) A method for forming a pathway from a sub-intimal space of a blood
2 vessel into a true lumen of the blood vessel, comprising:
3 positioning a catheter system within the sub-intimal space at a position proximate
4 to a target entry site into the vessel true lumen, the catheter system including at least one
5 lumen in communication with at least one port in a distal region of the catheter system,
6 the catheter system further including an internal excising element that is translatable
7 across a portion of the port;
8 determining a radial position of the true lumen with respect to the port at the
9 target entry site from a position in the sub-intimal plane using an imaging device of the
10 catheter system;
11 advancing the internal excising element along a portion of the port; and
12 excising an area of tissue separating the sub-intimal space from the true lumen
13 using the excising element, the excised area of tissue generating a pathway from the sub-
14 intimal space to the true lumen.

1 21. (New) A method for forming a pathway from a sub-intimal space of a blood
2 vessel into a true lumen of the blood vessel, comprising:
3 positioning a catheter system within the sub-intimal space at a position proximate
4 to a target entry site into the vessel true lumen, the catheter system including at least one

5 lumen in communication with at least one port in a distal region of the catheter system,
6 the catheter system further including an internal excising element that is translatable
7 across a portion of the port;
8 advancing the internal excising element along a portion of the port; and
9 excising an area of tissue separating the sub-intimal space from the true lumen
10 using the excising element, the excised area of tissue generating a pathway from the sub-
11 intimal space to the true lumen.

1 22. (New) A method for establishing a pathway through a chronic total occlusion of a
2 blood vessel, the pathway connecting a first region of a true lumen of the blood vessel
3 which is proximal to the occlusion to a second region of the true lumen of the blood
4 vessel distal to the occlusion via an extra-luminal pathway within the vessel, comprising:
5 forming a track longitudinally from the first region of the true lumen through the
6 occlusion and into a sub-intimal space distal to the occlusion;
7 positioning a catheter system within the sub-intimal space using the track, the
8 catheter system including at least one lumen in communication with at least one port in a
9 distal region of the catheter system, the catheter system further including an internal
10 incising element that is translatable across a portion of the port;
11 determining a radial position of the true lumen with respect to the port using an
12 imaging device of the catheter system; and
13 forming an incision in tissue separating the sub-intimal space from the true lumen
14 using the incising element, the incision having separate and distinct end points and
15 forming a pathway between the sub-intimal space and the true lumen, wherein the tissue
16 remains external to the port subsequent to forming the incision.

1 23. (New) A method for establishing a pathway through a chronic total occlusion of a
2 blood vessel, the pathway connecting a first region of a true lumen of the blood vessel
3 which is proximal to the occlusion to a second region of the true lumen distal to the
4 occlusion via an extra-luminal pathway within the vessel, comprising:
5 forming a track longitudinally from the first region of the true lumen through the
6 occlusion and into a sub-intimal space distal to the occlusion;

7 positioning a catheter system within the sub-intimal space using the track, the
8 catheter system including at least one lumen in communication with at least one port in a
9 distal region of the catheter system;

10 determining a radial position of the true lumen with respect to the port using an
11 imaging device of the catheter system;

12 applying a vacuum through the catheter lumen and the port, evacuating fluid from
13 the sub-intimal space and bringing the sub-intimal tissue into intimate contact with the
14 port; and

15 advancing a working element through the port and through the tissue separating
16 the sub-intimal space and the second region of the true lumen and generating a pathway
17 from the sub-intimal space to the second region of the true lumen.

1 24. (New) A catheter system for use in forming a pathway between a sub-intimal
2 space of a blood vessel and a true lumen of the blood vessel, comprising:

3 a catheter body including a proximal end, a distal end, and at least one lumen
4 configured to track over a guide wire to a location in vasculature;

5 a distal endpiece coupled to the distal end of the catheter body, the endpiece
6 including at least one port in communication with the lumen;

7 an imaging device for use in aligning a radial position of at least one of the
8 catheter body and the endpiece in the sub-intimal space relative to the true lumen; and

9 an incising element translatable across a portion of the port and configured to
10 form an incision in tissue separating the sub-intimal space from the true lumen, the
11 incision having separate and distinct end points and forming a pathway between the sub-
12 intimal space and the true lumen, wherein the tissue remains external to the port
13 subsequent to forming the incision.

1 25. (New) The system of claim 24, wherein the imaging device is a rotational device.

1 26. (New) The system of claim 24, wherein the imaging device is an ultrasonic
2 device.

- 1 27. (New) The system of claim 24, wherein the imaging device is an optical
2 coherence tomography (OCT) device.
- 1 28. (New) The system of claim 24, wherein the cutting element is separate from and
2 arranged externally concentric to the imaging device.
- 1 29. (New) The system of claim 24, wherein the incising element is affixed to the
2 imaging device.
- 1 30. (New) The system of claim 24, wherein the imaging device is a phased-array
2 device located on the catheter body and in registration with the port.
- 1 31. (New) The system of claim 24, wherein the imaging device is a phased-array
2 device located on the distal endpiece and in registration with the port.
- 1 32. (New) The system of claim 24, wherein the catheter endpiece includes one or
2 more fluoroscopic areas for use in the aligning.
- 1 33. (New) The system of claim 24, wherein the lumen of the catheter body is
2 configured to translate a vacuum from the proximal end to the distal end and to the port.
- 1 34. (New) The system of claim 33, wherein the port is configured so that tissue
2 separating the sub-intimal space from the true lumen becomes invaginated into the port
3 upon application of the vacuum.
- 1 35. (New) The system of claim 24, wherein the at least one port further includes a
2 distal port at a distal end of the endpiece, the distal port in communication with the lumen
3 for use in tracking over a guide wire.
- 1 36. (New) A catheter system for use in forming a pathway between a sub-intimal
2 space of a blood vessel and a true lumen of the blood vessel, comprising:

3 a catheter body including a proximal end, a distal end, and at least one lumen
4 configured to track over a guide wire to a location in vasculature;
5 a distal endpiece coupled to the distal end of the catheter body, the endpiece
6 including at least one port in communication with the lumen; and
7 an incising element translatable across a portion of the port and configured to
8 form an incision in tissue separating the sub-intimal space from the true lumen, the
9 incision having separate and distinct end points and forming a pathway between the sub-
10 intimal space and the true lumen, wherein the tissue remains external to the port
11 subsequent to forming the incision.

1 37. (New) A catheter for use in forming a pathway between an intravascular
2 dissection track advanced through a vascular total occlusion to an extra-luminal space
3 distal to the occlusion and a true lumen of a blood vessel, comprising:
4 a catheter body including a proximal end, a distal end, and at least one catheter
5 lumen configured to track over a guide wire to a target vascular location, the catheter
6 lumen configured to translate vacuum from the proximal end to the distal end;
7 a distal termination coupled to the distal end of the catheter body, the distal
8 termination including at least one port in communication with the lumen, the port
9 configured to receive the vacuum via the catheter lumen;
10 imaging means configured to determine a radial position of the catheter in the
11 extra-luminal space with respect to a location of the true lumen and to align the port to
12 the true lumen; and
13 an incising element translatable across a portion of the port and configured to
14 incise a flap in tissue separating the extra-luminal space from the vessel true lumen to
15 form the pathway between the extra-luminal space and the vessel true lumen at a location
16 distal to the occlusion.

1 38. (New) A catheter system for use in forming a pathway between a sub-intimal
2 space of a blood vessel and a true lumen of the blood vessel, comprising:

3 a catheter body including a proximal end, a distal end, and at least one lumen
4 configured to track over a guide wire to a location in vasculature, the catheter lumen
5 configured to translate vacuum from the proximal end to the distal end;
6 a distal endpiece coupled to the distal end of the catheter body, the endpiece
7 including at least one port in communication with the lumen; and
8 an incising element translatable across a portion of the port and configured to
9 form an incision in tissue separating the sub-intimal space from the true lumen, the
10 incision having separate and distinct end points and forming a pathway between the sub-
11 intimal space and the true lumen, wherein the tissue remains external to the port
12 subsequent to forming the incision.

1 39. (New) A catheter system for use in forming a pathway between a sub-intimal
2 space of a blood vessel and a true lumen of the blood vessel, comprising:

3 a catheter body including a proximal end, a distal end, and at least one lumen
4 configured to track over a guide wire to a location in vasculature;

5 a distal endpiece coupled to the distal end of the catheter body, the endpiece
6 including at least one port in communication with the lumen; and

7 an excising element translatable across a portion of the port and configured to
8 excise tissue separating the sub-intimal space from the true lumen to form a pathway
9 between the sub-intimal space and the true lumen.

1 40. (New) The system of claim 39, further comprising an imaging device for use in
2 aligning a radial position of at least one of the catheter body and the endpiece in the sub-
3 intimal space relative to the true lumen.

1 41. (New) The system of claim 39, wherein the catheter lumen is configured to
2 translate vacuum from the proximal end to the port.

1 42. (New) A device for use in forming a pathway from a sub-intimal space of a blood
2 vessel into a true lumen of the blood vessel, comprising:

3 means for positioning a catheter system within the sub-intimal space at a position
4 proximate to a target entry site into the vessel true lumen, the catheter system including at
5 least one lumen in communication with at least one port in a distal region of the catheter
6 system, the catheter system further including an internal incising element that is
7 translatable across a portion of the port; and
8 means for forming an incision in tissue separating the sub-intimal space from the
9 true lumen using the incising element, the incision having separate and distinct end points
10 and forming a pathway between the sub-intimal space and the true lumen, wherein the
11 tissue remains external to the port subsequent to forming the incision.